

II. REMARKS

Formal Matters

Claims 1-4 and 7-30 are pending after entry of the amendments set forth herein.

Claims 1, 5-9, 11, 12, 19, 20, 23, 24, and 26-29 were examined and were rejected. Claims 2-4, 10, 13-18, 21, 22, 25, and 30 were withdrawn from consideration.

Claims 1, 11, and 19 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claims 1, 11, and 19 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claim 1: page 9, lines 22-31, and page 18, line 28 to page 19, line 5; claim 11: page 9, lines 22-31; and claim 19: page 8, lines 16-19. Accordingly, no new matter is added by these amendments.

Claims 5 and 6 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Claim objection

Claim 1 was objected to. The Office Action stated that the claim recites material directed to non-elected inventions. Applicants respectfully traverse the objection.

The Office Action which issued on September 11, 2006 in this application included a Restriction Requirement and an Election of Species Requirement. In response to the Restriction Requirement, Applicants elected Group I (claims 1-12, 18-20, and 23-29). Thus, claim 1 is not directed to a non-elected invention.

The Election of Species requirement in item 6 of the September 11, 2006 Office Action required that Applicants elect one of: a) antibody specific to *Actinomyces* species; and b) antibody to *Lactobacillus* species. Applicants elected (b).

As noted in the September 11, 2006 Office Action, upon allowance of a generic claim, Applicants are entitled to consideration of claims to additional species.

There is no requirement that Applicants delete non-elected species from a generic claim. As such, claim 1 need not be amended to delete reference to the non-elected species.

Rejection under 35 U.S.C. §101

Claim 19 was rejected under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter.

The Office Action stated that adding “isolated” or some similar recitation would be sufficient to overcome this rejection.

Claim 19 is amended to recite an “isolated cell.”

Applicants submit that the rejection of claim 19 under 35 U.S.C. §101 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §112, first paragraph

Claim 9 was rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. Claims 34, 41, and 43 rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

Claim 9

The Office Action stated that the antibodies SWLA4 and SWLA5 are required in order to practice the invention; and stated that the deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention.

Without conceding as to the correctness of this rejection, Applicants note that the SWLA4 and SWLA5 hybridoma cell lines are being prepared for deposit. Once the SWLA4 and SWLA5 hybridoma cell lines are deposited, a Declaration Regarding Biological Deposit will be submitted.

Claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29

The Office Action stated that the claims are drawn to a genus of antibodies, the members of which recognize *Lactobacillus* species generally, and *Lactobacillus casei* specifically. The Office Action stated that Applicant has failed to fully characterize the antigen to which the claimed antibody binds. Applicants respectfully traverse the rejection.

The instant antibodies as claimed do not require any knowledge of a specific cell surface antigen on a cariogenic bacterium. All that is required is that the antibody bind specifically to a cell surface antigen on a cariogenic bacterium. As discussed in the instant specification, an antibody that binds

specifically to a cariogenic bacterium, e.g., the antibody binds almost exclusively to the specific cariogenic bacterium and not to any other cariogenic bacterium. Specification, page 4, lines 10-31.

The instant specification describes making hybridomas to formalinized *A. naeslundii* (ATCC 12104) and *L. casei* (ATCC 11578). Specification, page 18, lines 28-29. The instant specification also describes use of an enzyme-linked immunosorbent assay (ELISA) for detecting hybridoma culture supernatants containing antibodies reactive with the corresponding bacteria. Specification, page 18, lines 30-33. The instant specification further describes how the antibodies were tested for cross-reactivity with a panel of bacteria shown in Table 1. Specification, page 19, lines 2-3; and Table 1, page 26. The instant specification then describes use of the antibodies to detect *A. naeslundii* or *L. casei*. Specification, page 19, line 10 to page 22, line 33. No knowledge of any particular epitope is required in order to use the antibodies to detect cariogenic bacteria.

Given the description in the specification, including the working examples, those skilled in the art would recognize that Applicants were in possession of antibodies that specifically bind a cariogenic bacterium. As such, claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29 are in compliance with the written description requirement of 35 U.S.C. §112, first paragraph.

Claims 34, 41, and 43

The instant application currently does not include claims numbered 34, 41, and 43. Applicants respectfully request clarification of the rejection.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejection of the claims discussed above under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 5-9, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

Claim 1

The Office Action stated that claim 1 is vague and indefinite by use of “high specificity and

sensitivity.”

Claim 1 is amended to delete the phrase “high specificity and sensitivity.”

Claims 9, 11, and 12

The Office Action stated that claims 9, 11, and 12 are vague and indefinite in the recitation of SWLA4 and SWLA5. The Office Action stated that it is unclear whether Applicant is referring the antibodies produced by the SWLA4 and SWLA5 hybridomas, or some other antibodies.

As is apparent from the specification, the designations “SWLA4 and SWLA5” refer to both hybridomas and monoclonal antibodies produced by the SWLA4 and SWLA5 hybridomas. As such, claims 9, 11, and 12 are clear.

Claim 11

The Office Action stated that claim 11 is vague and indefinite by the use of “at least substantially the same sensitivity and specificity of SWLA5.”

Without conceding as to the correctness of this rejection, claim 11 is amended to recite that the antibody binds specifically to *Lactobacillus casei* and competes at least about 80% as effectively on a molar basis with SWLA5 for binding to *L. casei*.

Applicants submit that the rejection of claims 1, 5-9, 11, 12, 19, 20, 23, 24, and 26-29 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §102(b) or §103(a)

Claims 1, 5-8, 11, 19, 20, 24, and 27-29 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ziola et al. ((2000) *J. Am. Soc. Brew. Chem.* 58:63-68; “Ziola”) or, in the alternative, under 35 U.S.C. §103(a) as allegedly obvious over Ziola. Claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ralls et al. (WO 00/73492; “Ralls”), or, in the alternative, under 35 U.S.C. §103(a) as allegedly obvious over Ralls.

Claims 1, 5-8, 11, 19, 20, and 27-29 over Ziola

The Office Action stated that Ziola discloses monoclonal antibodies to *Lactobacillus* species, including *Lactobacillus casei* strain. Applicants respectfully traverse the rejection.

Claim 1 recites an antibody that recognizes a cell surface antigen of a target **cariogenic** bacterium. Ziola neither discloses nor suggests any antibodies that bind a cell surface antigen of a **cariogenic** bacterium. Ziola is concerned with beer spoilage bacteria, not cariogenic bacteria. As such, Ziola cannot anticipate or render obvious any of claims 1, 5-8, 11, 19, 20, 24, and 27-29.

Claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29 over Ralls

The Office Action stated that Ralls discloses monoclonal antibodies to *Lactobacillus* species and the use of the antibodies in immunoassays. Applicants respectfully traverse the rejection.

Ralls does not disclose or suggest any antibodies that specifically bind a cell surface antigen of a *Lactobacillus* species cariogenic bacterium. Ralls provides two examples: Example 1 describes an immunoassay using polyclonal antibody to *Streptococcus mutans*; and Example 2 describes an immunoassay using polyclonal antibody to *Lactobacillus sp.* There is no specificity disclosed or discussed in Ralls. As such, Ralls cannot anticipate or render obvious any of claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29.

Conclusion as to the rejections under 35 U.S.C. §102(b) or §103(a)

Applicants submit that the rejection of the claims discussed above under 35 U.S.C. §102(b) or §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCLA-007.

Respectfully submitted,
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